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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,938	06/25/2001	Graham P. Allaway	50875-DA/JPW/SHS	9272

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EXAMINER	
BROWN, TIMOTHY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,938	ALLAWAY ET AL.	
	Examiner	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09 September 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

This Non-Final Office Action is responsive to the communication received September 9, 2004. Claims 51-58 are under examination. Claims 1-50 have been canceled.

Telephonic Interview

During a telephonic interview on January 28, 2005, it was agreed that the Notice of Non-Compliant Amendment mailed November 30, 2004 was in error because the referenced amendment was properly signed. It was also agreed that the shortened statutory response period would be restarted as of the mailing date of this Non-Final Office Action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 7, 2004 in compliance with the provisions of 37 CFR 1.97. The IDS has been considered and its references made of record. The IDS has been initialed, signed and attached to this Office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 51-58 are provisionally rejected under the judicially created doctrine of double patenting over (1) claims 15 and 16 of copending Application No. 09/412,284, (2) claims 18 and 20 of copending Application No. 09/852,236, and (3) claims 1-5, 18 and 31 of copending Application No. 10/371,483. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Claims 51-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15 and 16 of copending Application No. 09/412,284. Although the conflicting claims are not identical, they are not patentably distinct from one another. Claims 51-58, and copending claims 15 and 16, are drawn to an antibody that is specific for the CCR5 receptor. Claims 51-58 differ from copending claims 15 and 16 in that claims 51-58 fail to recite a number of properties listed in the copending claims. However, it would have been prima facie obvious to omit these features given that they fail to structurally distinguish the antibody of claims 51-58.

Claims 51-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18 and 20 of copending Application No. 09/852,236 in view of Young et al.. Although the conflicting claims are not identical, they are not patentably distinct from one another. Claims 51-58 and copending claims 18 and 20 are drawn to an agent that binds the CCR5 receptor. Claims 51-58 differ from copending claims 18 and 20 in that the copending claims fail to require the agent to be an antibody. However, Young et al. teach an antibody directed against a virus-associated cell

surface protein (col. 2, lines 66-67; and col. 3, lines 1-2). It would have been obvious to modify copending claims 18 and 20 to include an antibody because Young et al. teach that anti-receptor antibodies provide a useful means for preventing viral attachment to target cells. Note that claim 21 of copending Application No. 09/852,236 was not included in this rejection even though it limits claim 20 by requiring an antibody. This is because it appears that claim 21 was intended to depend from claim 19 (claim 21 refers to the ligand of claim 19) which is not an obvious variant of claims 51-58.

Claims 51-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 18 and 31 of copending Application No. 10/371,483. Although the conflicting claims are not identical, they are not patentably distinct from one another. Claims 51-58 and copending claims 1-5, 18 and 31 are both drawn to an antibody that is specific for the CCR5 receptor. Claims 51-58 differ from copending claims 1-5, 18 and 31 in that copending claims 1-5, 18 and 31 require specific expression products from a number of plasmids. However, it would have been obvious to omit the specific sequences required by copending claims 1-5, 18 and 31. One skilled in the art would readily recognize that vaccinating animals with the CCR5 polypeptide would provide an easier for producing anti-CCR5 antibody than the method used to produce the antibody of the copending claims. Therefore, it would have been obvious to modify obvious to omit the specific sequences required by copending claims 1-5, 18 and 31 to in order to simplify the production of the CCR5 antibody.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51-58 are indefinite in the recitation of "[a]n isolated antibody *capable of binding. . .* and inhibiting" This language fails to clearly indicate whether in fact the isolated antibody has the recited binding and inhibiting properties. Appropriate correction is required.

35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-58 are rejected under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

Undue experimentation is defined by the following factors: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of

working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

The state of the art as of Applicants' priority date shows that *in vivo* therapy for inhibiting HIV infection generally relied on nucleoside analogs such as AZT (FASEB J. (September 1995) 9, 1157-1163). An HIV treatment based on an anti-chemokine receptor antibody was neither suggested nor practiced in the art. At most, the art demonstrated that some beta-chemokines were capable of disrupting HIV infection *in vitro* (Science (1995) 270, 1811-1815). Thus, one skilled in the art could not easily predict how to suppress HIV infection *in vivo* using a therapy based on anti-chemokine receptor antibodies. The art that came closest to suggesting such a therapy showed that RANTES, MIP-1 beta and MIP-1 alpha had some ability to disrupt the infection of CD4+ clones *in vitro* using laboratory strains of HIV (id). However, these effects were inconsistent (see e.g. p1813, ¶ 1; and Fig. 2B) and failed to suggest the use of anti-chemokine receptor *antibodies* would inhibit HIV infection *in vivo*. Based on the unpredictability of using anti-chemokine receptor antibodies to inhibit HIV infection *in vivo*, one skilled in the art would have to rely heavily on the specification in order to practice the claimed invention. The specification however fails to provide adequate direction for reducing the claimed antibody to practice. While the specification makes passing references to an anti-chemokine receptor antibody (see page 12, lines 10-13; and p. 17, line 5), the majority of the specification relates to CCR5 antagonists that compete with gp120 for the CCR5 receptor. This also applies to Applicants' working examples which show the effect of chemokines and non-chemokine peptide antagonists on HIV attachment and entry *in vitro*. The specification does not teach an antibody that is specific for the chemokine receptor antibody, let alone an antibody that

is capable of inhibiting HIV infection *in vivo*. Applicants' specification also fails to teach the motifs and/or regions of the CCR5 receptor that are involved in supporting HIV attachment and entry. Given the unpredictability of using anti-chemokine receptor antibodies noted above, and the specification's failure to teach or suggest such an antibody, practicing the invention as claimed would require undue experimentation.

It should be noted that the specification also fails to enable the range of chemokine receptor antibodies that are claimed. The claims are drawn to an antibody that recognizes any human chemokine receptor on the surface of a DC4+ cell that inhibits the infection of CD4+ cells by HIV. However, Applicants have only disclosed the CD4+ CCR5 receptor as capable of modulating HIV infection. Applicants have not disclosed any other chemokine receptors that modulate HIV infection of CD4+ cells. The claims therefore also lack enablement the range of chemokine receptor antibodies presently claimed.

Claims 51-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants' claims lack adequate written description for the following two reasons.

First, Applicants have not disclosed a representative number of chemokine receptors that are capable of modulating HIV infection. Applicants' claims are drawn to an antibody that is specific for "*a* human chemokine receptor on the surface of a CD4+ cell . . . ." However, Applicants have only disclosed the CCR5 receptor as being involved in HIV infection. The

claims therefore lack written description for a representative number of CD4+ chemokine receptors.

Second, the claims lack written description for a representative number of antibodies that are specific for CD4+ chemokine receptors. Not only does the specification lack support for a representative number of chemokine receptors, it also lacks support for a representative number of antibodies that are specific for these receptors. The specification does not disclose the chemokine receptor (i.e. CCR5) epitopes with adequate detail to allow one skilled in the art to conclude that Applicants possessed the range of antibodies presently claimed; there is no disclosure of the extracellular motifs and/or regions of CD4+ chemokine receptor regions that would allow an antibody to prevent coreceptor activity. Disclosure of the regions involved in the binding of chemokine receptor ligand is also lacking. Based on this lack of disclosure, one skilled in the art could not reasonably conclude that the inventors possessed the range of antibodies presently claimed. The claims therefore lack written description for a representative number of anti-chemokine receptor antibodies.

Conclusion

A shortened statutory period for reply to this non-final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
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